

PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Applicant's or agent's file reference see form PCT/ISA/220		Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)	
International application No. PCT/L2004/000433	International filing date (day/month/year) 20.05.2004	Priority date (day/month/year) 22.05.2003	
International Patent Classification (IPC) or both national classification and IPC A61F200			
Applicant CONTIPI LTD.			

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority *18.06.2004 - 2003*
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for International preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/L2004/000433

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - in written format
 - in computer readable form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
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Box No. II Priority

1. The following document has not been furnished:

- copy of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(a)).
- translation of the earlier application whose priority has been claimed (Rule 43bis.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	13, 19 - 22, 28 - 36, 43 - 45
	No: Claims	1-12, 14 - 18, 23 - 27, 38 - 42, 46 - 49
Inventive step (IS)	Yes: Claims	
	No: Claims	1 - 49
Industrial applicability (IA)	Yes: Claims	1 - 49
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 The following documents are referred to in this communication:

- D1 : WO 00/67662 A (INTERNAL YOURS LLC) 16 November 2000 (2000-11-16)
- D2 : US 5 603 685 A (TUTRONE JR DONALD F) 18 February 1997 (1997-02-18)
- D3 : WO 02/26160 A (KIMBERLY CLARK CO) 4 April 2002 (2002-04-04)
- D4 : GB 2 352 181 A (MEDIWATCH LTD) 24 January 2001 (2001-01-24)
- D5 : US 4 307 716 A (DAVIS ALWYN K) 29 December 1981 (1981-12-29)
- D6 : US 6 418 930 B1 (FOWLER ROBERT STUART) 16 July 2002 (2002-07-16)
- D7 : EP 0 700 669 A (PETERS SA) 13 March 1996 (1996-03-13)

2 INDEPENDENT CLAIM 1

2.1 The present claim 1 does not meet the criteria of Article 33(1) PCT, because its subject-matter is not new in the sense of Article 33(2) PCT.
Document D1 discloses (the references in parenthesis applying to this document):

A device for minimizing involuntary urination in females adapted for being inserted into the vagina, comprising:

- (a) an internal support structure (20,32,44,116) comprising:
 - (I) at least one pressure providing member (24,34,44) capable of transition between a first collapsed position and a second expanded position, adapted for providing pressure, through the vaginal wall, on the mid-urethral region when being in the second position;
 - (ii) at least one anchoring member (26,36,46) adapted for anchoring the internal support structure following insertion of the device into the vagina, so as to prevent undesired movement of the device;
- (b) pulling member (6,104) for removal of the device from the vagina; so that when said pressure providing member (24,34,44) is in the collapsed position the internal device may be inserted or removed from the vagina; and when the device is inserted to the vagina said pressure providing member (24,34,44) may be transitioned to the second expanded position, so as to provide pressure through the vaginal wall on

the mid-urethra minimizing involuntary urination
(see page 11, lines 15 - 25; page 15, line 4 - page 16, line 9; page 20, line 20 - page 21, line 21; figures).

2.2 The attention of the applicant is drawn to the fact that each of the documents D2 (see column 3, lines 35 - 66; column 4, lines 27 - 44; column 7, lines 41 - 60; figures), D3 (see page 13, line 16 - page 14, line 26; figures), D4 (see page 2, line 1 - page 3, line 11; figures) and D5 (see column 2, line 49 - column 4, line 29; figures) disclose all the technical features of claim 1 and are prejudicial for its novelty as well.

3 DEPENDENT CLAIMS 2 - 49

3.1 Document D1 describes (see page 11, lines 15 - 25; page 15, line 4 - page 16, line 9; page 20, line 20 - page 21, line 21; figures) in combination with the technical features of claim 1 also the features of claims 2 - 5, 9, 17, 18, 23 - 26, 38 - 42 and 46 - 49. D2 describes (see column 3, lines 35 - 66; column 4, lines 27 - 44; column 7, lines 41 - 60; figures) the features of claims 7, 8, 10 - 12 and 14 - 16, D3 (see page 13, line 16 - page 14, line 26; figures) the features of claim 6 and D5 (see column 2, line 49 - column 4, line 29; figures) the features of claim 27. Therefore, the subject-matter of claims 2 - 12, 14 - 18, 23 - 27, 38 - 42 and 46 - 49 is not new.

3.2 The features of dependent claims 13, 19 - 22, 28 - 37 and 43 - 45 are not disclosed in combination with the features of the claims on which they depend in any of the available prior art documents. Therefore, these claims meet the requirements of Article 33(2) PCT.

3.3 However, the features of claim 13 are used for the same purpose in D2 (see column 3, lines 35 - 66; column 4, lines 27 - 44; column 7, lines 41 - 60; figures), the features of claim 19 in D6 (see column 7, line 44 - column 8, line 54; figures 4 - 6), the features of claims 34 - 36 in D7 (see column 6, lines 17 - 42; figures) and the features of claim 43 in D5 (see column 2, line 49 - column 4, line 29; figures). Therefore, the claims 13, 19, 34 - 36 and 43 do not fulfill the requirements of inventive step, Article 33(3) PCT.

3.4 The features in claims 20 - 22, 28 - 33, 37, 44 and 45 are merely one of several straightforward possibilities from which the skilled person would select, in accordance

with circumstances, without the exercise of inventive skill, in order to solve the problem posed and therefore do not fulfill the requirements of Article 33(3) PCT.

3.5 The device described in the present claims is industrial manufacturable and therefore the requirements of Article 33(4) PCT are fulfilled.

Re Item VII

Certain defects in the international application

1. Independent claim 1 should be cast in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT). In this case it appears that at least all the features of present claim 1 should form the preamble of a new independent claim.
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. Claim 35 is made dependent on claim 30 and not 34 as only in claim 34 the telescopic arms are mentioned.

Re Item VIII

Certain observations on the international application

1. Claims 21 and 22 refer to "a balloon" which is not the same balloon as mentioned in claim 20. In view of that, it seems that the matter of said claims is directed to a device comprising two balloons, which is not the case. Therefore, these claims do not meet the requirements of Article 6 PCT.
2. Claim 45 merely states that the device is "disposable" and does not specify any technical feature of the device, see Rule 6.3(a) PCT and is therefore not clear in view of Article 6 PCT.
3. Claim 47 relates to a method of using the apparatus rather than clearly defining

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the apparatus in terms of its technical features. The intended limitations are therefore not clear from this claim, contrary to the requirements of Article 6 PCT.